DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

June 7, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-22

Roger Grummel, President
Sea Products West
(Flying Fish Express)
851 Coho Way, Suite 304
Bellingham, Washington 98225

WARNING LETTER

Dear Mr. Grummel:

On February 11, 1999, the Food and Drug Administration (FDA) conducted an inspection of Flying Fish Express located at 7937 2nd Avenue South, Seattle, Washington. At the conclusion of the inspection, Jeff C. Jacobsen, Operations Manager, was presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the scombroid species finfish processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. Our investigator found that your firm is monitoring for the presence of ice or frozen gel packs. However, the critical limit for this procedure is not listed in your firm's HACCP plan for fresh fish (which includes scombroid species) as required by 21 CFR Part 123.6(c).

2. Your firm failed to develop an appropriate corrective action plan for a deviation from the critical limit for the histamine (scombrotoxin) formation hazard identified in your firm's HACCP plan at the Storage critical control point, 21 CFR Part 123.7(b). The corrective action plan listed in your firm's HACCP plan does not include the steps necessary to ensure that the product is not injurious to health. To address the possibility of unsafe product, your firm should either destroy the product, divert the product to a non-food use, or collect and analyze a representative sample for histamine and reject the product if any unit exceeds 50 ppm histamine.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure

that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

for Roger L. Lowell
District Director

3 Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement